



A COMPARATIVE STUDY OF COLLAGEN DRESSING VERSUS CONVENTIONAL DRESSING IN CHRONIC NON-HEALING ULCERS.

General Surgery

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ABSTRACT

Background: Foot ulcer is a major disease – causing disability to many patients around the world. Treatment of foot ulcer remains a major health care issue; & especially diabetic foot ulcer accounts for 15 % of incidence which is the commonest cause of lower extremity amputation accounts for. Effective treatment of ulceration is necessary to reduce the number of amputations as emphasized by St. Vincent's declaration. Therefore, evaluation of the effect of collagen dressing on various type of foot ulcers is undertaken. The aim of the study is to compare the effectiveness of collagen dressing in healing of these ulcers in comparison with the conventional wound dressings. **Materials & methods:** The study was conducted in 100 patients in S.V.R.R.G.G.H Hospital, Tirupathi in department of general surgery, after obtaining consent from the patients. Patients admitted in the department of General surgery with the diagnosis of chronic non-healing ulcers were taken into this study. The study was conducted on total hundred patients with chronic ulcer, who reported at S.V.R.R.G.G.H., Tirupathi. Patients with chronic non-healing ulcers attending the department of general surgery were invited to participate in the study & written informed consent was taken. All patients underwent a standard clinical & laboratory evaluation. Briefly, information about age, known DM duration, smoking habits, arterial blood pressure, & anthropometric measurements was collected. In all patients, wound size was noted before treatment initiation. A collagen or conventional dressings were applied to wound, and all patients were followed as per standard post-application treatment protocol. Patients underwent dressing changes every 3 to 4 days until wound healing or for maximum period of 12 weeks. Changes of wound size were recorded when the dressing was removed. Healing time, duration of antibiotic therapy, follow up period were noted. All patients were also followed up for adverse events. All the data were captured in the printed proforma & compared. **Results:** Collagen dressing increases the rate of wound healing as compared to moistened gauze. It also reduces the requirement of skin cover. Further, it also reduces the followup period & antibiotic use significantly as compared to conventional dressing. **Conclusion:** Because of simple method of application, better tolerance, non-allergic, safe & enhances wound healing, hence collagen can be recommended as a temporary biological dressing material. Collagen dressing is safe & effective in the treatment of foot ulcer & significantly reduces healing time, duration of antibiotic therapy & follow up time.

KEYWORDS

INTRODUCTION

Non-healing ulcers are a major health problem worldwide and have great impact at personal, professional and social levels, with high cost in terms of human and material resources. Recalcitrant non-healing ulcers are inevitable and detrimental to the lower limb and are a major cause of non-traumatic lower limb amputation¹.

During the last decade, various new dressing materials developed, like calcium alginate, hydro-colloid membranes and fine mesh gauze. These have a disadvantage in that they become permeable to bacteria. Biological dressings like collagen on the other hand, create the most physiological interface between the wound surface and environment, and are impermeable to bacteria. Collagen dressings have other advantages over conventional dressings in terms of ease of application and being natural, non-immunogenic, non-pyrogenic, hypo-allergenic, and pain-free. The present study has been conducted to compare the efficacy of collagen dressing with that of conventional dressing materials like silver sulfadiazine, nadifloxacin, povidone iodine, or honey (used traditionally), in the management of chronic wounds including those due to burns².

The development of collagen dressings is only logical given its unique structural and functional characteristics. Collagens are the most abundant and ubiquitous proteins in vertebrates. In addition to providing mechanical support to the connective tissue, the collagens form an essential substrate for cellular adhesion and migration. Therefore, collagen is considered to be an important factor in the regenerative process.

Collagen is hemostatic, has low antigenicity, and supports cellular growth. The importance of collagen in burn wound healing has been appreciated for a long time. Wound healing and regeneration involves cell proliferation, cell migration, cell differentiation and interaction between the different components in which collagen may affect healing not only at the final stage but also in the very early stage of healing. Clinical trials were performed with the fabricated collagen membranes on burn wounds and the results show the advantages of the collagen membranes in burn wound healing³.

Collagen sheet is prepared from bovine collagenous tissue by treating tissues with a series of chemical and enzymatic procedures. This is followed by chemical cross-linking, packing, and sterilization.

Collagen sheet is retained in the tissue and gradually absorbed by inflammatory cellular activity; the fibrous tissue is replaced by fibroblasts. Granulation tissue developed at a normal rate and the cellular events were precisely the same as those occurring in normal wounds. Collagen is well recognized as a useful and important biopolymer in the field of biomaterial engineering. In order to gain satisfactory results from collagen when used as a biomaterial, its physical and biological properties prove necessary. Desamidation of collagen is one such approach that develops better biomaterial with minimal alterations in collagen's native properties.

Desamidation of hide trimmings and Achilles tendons resulted in a modified form of collagen. It improved the solubility as well as the swelling properties of the biomolecule, which are prerequisites for a biomaterial. Collagen contains moderate amounts of positively and negatively charged groups derived from the diamino dicarboxylic acids built into the molecule. The collagen molecule contains 45 aspartic acids, 72 glutamic acids, and 37 lysine and 45 arginine residues. These residues are polar in nature and, on dissociation, the carboxyl groups are negatively charged. In the isoelectric state and in equilibrium with water in the pH range from 5.5 to 9.5, these polar groups are completely ionized. Collagen is an amphoteric ionic structure attaining the highest degree of charge, both positive in the isoelectric pH range, i.e. around 7.0 for collagen. Desamidation causes progressive hydrolysis of amide groups of asparagines and solubility of collagen. Desamidation collagen has high viscosity and a very high hydroxyproline content, like native collagen⁴.

Aim of the study :

To study & compare the effectiveness of collagen dressing with conventional dressings in patients with chronic non-healing ulcers.

Objectives of the study :

To study & compare the effectiveness of collagen dressing with conventional dressings in patients with chronic non-healing ulcers, with respect to

- Ulcer healing time
- Reduction in size of ulcer
- Duration of hospitalisation
- Duration of Antibiotic therapy required
- Any adverse events reported with collagen/conventional dressings

MATERIALS & METHODS :

Type of The Study : Prospective hospital based comparative study

Study Subject : Patient with diagnosis of chronic non-healing ulcers

Number of Groups : 2

Study Population : 100

Sample Method : randomised sampling

Study Period : 1 YEAR

Inclusion Criteria:

1. Patients with chronic ulcers including diabetes & burns.
2. Patients who are accepting to give informed consent
3. Patient above 18 years age.

Exclusion Criteria :

1. Patient who are critically ill.
2. Patient with any evidence of underlying bone osteomyelitis.
3. Malignancy
4. Patient refusal

Study Method :

The study was conducted on total 100 patients with chronic ulcer, reported at S.V.R.R.G.G.H , Tirupathi. Patients with chronic ulcers attending the surgery department were invited to participate in the study and written informed consent was taken. All patients were subjected to routine investigations. Shortly, information about age, known DM duration, smoking habits, arterial blood pressure, and anthropometric measurements was collected. In all patients, wound size was recorded before the start of treatment. A collagen or conventional dressing was applied to wound, and all patients were followed as per standard post-application treatment guidelines.

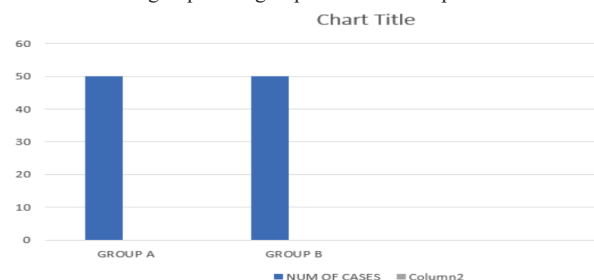
Every 3 to 4 days, dressing was changed until wound healing or for maximum period of 12 weeks. Changes in wound size were recorded after removal of dressing. Healing time, follow up period, duration of antibiotic therapy were recorded. Any adverse events with these dressing was also noted. All the data were recorded in the pre-printed pro-forma & compared.

Parameters Studied :

- a) Ulcer healing time
- b) Reduction in size of ulcer
- c) Duration of hospitalisation
- d) Duration of antibiotic therapy required
- e) Any adverse events reported with collagen/conventional dressings.

Results & Analysis :

This study includes 100 samples, 100 patients who were attending general surgery OPD over a period of two years. Patients with chronic ulcers including diabetes & burns were included in this study. Each divided into two groups. Each group contains 50 samples.



Number of Samples

GROUP A	GROUP B
50	50

Age & Incidence

There is increased incidence of ulcer in age group 35-70. In my study, youngest patient was 34 years & oldest patient was 77 years old.

Age in years	Collagen dressing	Conventional dressing	P value
0-35	3 (6 %)	3 (6 %)	<0.001
35-70	45 (90 %)	43 (86 %)	<0.001
>71	2 (4 %)	4 (8 %)	<0.001
Average	52.36	52.8	<0.001

Sex Distribution

In the present study, 71 patients were male & 29 patients were female. In this study, incidence of ulcers are more common in males.

MALE	FEMALE
71	29

Sex Distribution of Each Group

Type of dressing	Male	Female
Collagen dressing	34 (68 %)	16 (32 %)
Conventional dressing	37 (74 %)	13 (26 %)

Distribution of Cases By Etiology

Diabetic ulcer	Traumatic ulcer	Venous ulcer	Burns
55 (55 %)	39 (39 %)	4 (4 %)	2 (2 %)

Distribution of Patients Based On Etiology In Each Group

Type of etiology	Collagen dressing	Conventional dressing	P value
Diabetic ulcer	22 (44 %)	33 (66 %)	<0.001
Traumatic ulcer	23 (46 %)	16 (32 %)	<0.001
Venous ulcer	04 (8 %)	00 (0 %)	<0.001
Burns	01 (02 %)	01 (02 %)	<0.001

Comparison of Reduction In Size of Ulcer In Each Group

Comparison of initial size of ulcer

Size of ulcer cm2	Collagen dressing	Mean	SD	Conventional dressing	Mean	SD
15-25	10 (20 %)	11	10.8	03 (06 %)	10	11.3
25-35	27 (54 %)			27 (54 %)		
35-45	12 (24 %)			16 (32 %)		
>45	01 (02 %)			04 (08 %)		

Average initial size of ulcer in collagen dressing – 30.33 cm2

Average initial size of ulcer in conventional dressing – 33.75 cm2

Comparison of Reduced Size of Ulcer

Size of ulcer cm2	Collagen dressing	mean	SD	Conventional dressing	Mean	SD
1-3	37 (74 %)	6.5	17.5	9 (18 %)	10.5	8.96
3-6	13 (26 %)			25 (50 %)		
6-9	0 (0 %)			12 (24 %)		
>9	0 (0 %)			04 (08 %)		
Average	2.26 cm2			5.3 cm2		

Comparison of Ulcer Healing Time of Both Groups

Duration in days	Collagen dressing	Mean	SD	Conventional dressing	Mean	SD	P value
11-20	4 (08 %)	4	11.07	0	8	9.7	<0.001
20-30	23 (46 %)			8 (16 %)			<0.001
30-40	21 (42 %)			18 (36 %)			<0.001
40-50	2 (04 %)			22 (44 %)			<0.001
>50	0			2 (04 %)			<0.001

Average ulcer healing time in collagen dressing group – 28.14 days

Average ulcer healing time in conventional dressing group – 39.28 days

Duration of Hospitalisation In Both Groups

Duration in days	Collagen dressing	Conventional dressing	P value
10-20	3	-	<0.001
20-30	23	1	<0.001
30-40	22	25	<0.001
40-50	2	22	<0.001
50-60	-	2	<0.001
average	29.24 days	40.32 days	<0.001

Duration of Antibiotic Therapy In Both The Groups

Duration in days	Collagen dressing	Conventional dressing	P value
10-20	50(100%)	48 (96%)	<0.001
20-30	0	01(2%)	
30-40	0	01(2%)	
Average	8.22 days	13.78 days	

DISCUSSION

In our study of total 100 patients, 55 patients had ulcer due to diabetes, 39 patients had ulcer due to trauma, 4 patients had venous ulcer, 2 patients had burns ulcer. In our study, diabetic ulcers are higher, which clearly indicates most common ulcers are due to diabetes.

Infection of the wound is one of the most common complications in burns, & presence of dirt in abrasions as most of them are traumatic. Infection in turn leads to delayed healing of the wound. Reduction in the infection rate improves the quality of life.

In our study, collagen dressing decreases infection rate compared to conventional dressing. Out of 100 samples only 8 people who underwent conventional dressing suffered infection.

Duration of antibiotic therapy needed in collagen dressing patient is relatively lower than conventional dressing patients. Patients who underwent collagen dressing, requirement of antibiotic therapy is less than 20 days with an average of 8 days. Patients who underwent conventional dressing, requirement of antibiotic therapy is more than 20 days with an average of 13 days. Hence, use of antibiotics can be limited for lesser period in collagen dressing.

Similarly, duration of hospital stay is also less in collagen dressing undergoing patients. Reduced wound size of collagen dressing averages 2.26 cm² & of conventional dressing is 5.3 cm², so collagen dressing decreases the wound size significantly compared to conventional dressing. Thus theoretically, collagen dressing is an advantageous alternative to the moistened gauze that is the routine standard of care.

SUMMARY & CONCLUSION

Bases on our study on 100 patients in general surgery department of S.V.R.R.G.G.H., it is found that collagen dressing is more effective than conventional dressing in a chronic non-healing ulcer.

It also reduces the follow up period, duration of hospital stay, duration of antibiotic therapy, is significantly reduced in collagen dressing when compared to conventional dressing. It is because its spongy network causes exudate absorption & blocking of possible extensions of the wound, thus prevents bacterial growth that would delay the healing process.

It reduces the requirement of SSG. Better patient compliance as dressing need not to be changed regularly.

Because of simple method of application, better tolerance, non-allergic, safe, enhances wound healing, hence collagen can be recommended as temporary biological dressing material.

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